JUN 1 2 2007

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K062737

Company: Horiba ABX
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Date Prepared: 24th April 2007

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA CK NAC CP**
Common or Usual Name:	Total Creatine kinase
Device Class	Class II
Classification Name:	§862.1215 : Creatine Phosphokinase/Creatine kinase or isoenzymes Test System
Product Code:	CGS ; Nad reduction/Nadh oxidation, Cpk or isoenzymes

Trade/Proprietary Name:	**ABX PENTRA Myoglobin CP**
Common or Usual Name:	Myoglobin
Device Class	Class II
Classification Name:	§866.5680 : Myoglobin immunological Test System
Product Code:	DDR ; Myoglobin, antigen, antiserum, control

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA Myoglobin Cal**
Common or Usual Name:	Myoglobin Calibrator
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIT ; Calibrator, Secondary

Trade/Proprietary Name:	**ABX PENTRA Multical** (K060854)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA CK Control**
Common or Usual Name:	CK Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA Immuno II Control L/H**
Common or Usual Name:	Control Low/High
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA N Control** (K060854)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K060854)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent Predicate device
ABX PENTRA CK NAC CP	K834502
ABX PENTRA Myoglobin CP	K021229
ABX PENTRA Myoglobin Cal	K021229
ABX PENTRA Multical	K060854
ABX PENTRA CK Control	K954074
ABX PENTRA Immuno II Control L/H	K961828
ABX PENTRA N Control	K060854
ABX PENTRA P Control	K060854

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA CK NAC CP** is an in vitro diagnostic assay for the quantitative determination of total creatine kinase in human serum and plasma based on an optimized UV test. The assay is composed of a bi-reagent cassette, with 26 ml and 6.5 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Myoglobin CP** is an in vitro diagnostic assay for the quantitative determination of myoglobin in human serum and plasma based on a latex-enhanced immunoturbidimetric test. The assay is composed of a bi-reagent cassette, with 15 ml and 9.5 ml compartments. Reagents are chemical solutions with chemical additives and substances of animal origin.

The **ABX PENTRA Myoglobin Cal** is a liquid calibrator prepared from a dilution of purified myoglobin positive human sera. It is used for the calibration of the myoglobin assay. The assigned values are given on the vials. This calibrator is provided in five vials of 1 ml.

The **ABX PENTRA CK Control** is a lyophilized assayed control prepared from a bovine serum albumin with chemical additives and material of biological origin. It has to be used for the quality control of the creatine kinase assay. The assigned values are given in the enclosed annex. This calibrator is provided in 4 vials of 3 ml.

The **ABX PENTRA Immuno II Control L/H** is a lyophilized assayed control prepared from a stabilized pool of human sera. It has 2 levels (Low and High) to be used for the quality control of the myoglobin assay. The assigned values are given in the enclosed annex. Each level of this control is provided in one vial of 3 ml.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer.
This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

Intended Use :

All reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of their respective analytes : Total Creatine Kinase and Myoglobin using human serum and plasma.

The controls and calibrators are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX PENTRA CK NAC CP :	
Sample type	Serum & plasma
Detection limit	8 U/l
Accuracy and Precision	CV Total < 4.65%
Measuring range	8 U/l – 1500 U/l
Upper linearity limit	1500 U/l, and with automatic post-dilution : 4500 U/l
Correlation (n=350)	Y = 1.05 x - 1.75 with a correlation coefficient r^2 = 0.9930.
Calibration stability	8 days
Reagent stability	closed stability: 18 months at 2-8°C on-board stability (refrigerated area): 64 days

ABX PENTRA Myoglobin CP :	
Sample type	Serum & plasma
Detection limit	6.7 µg/l
Accuracy and Precision	CV Total < 5.24%
Measuring range	20.7 µg/l – 500 µg/l
Upper linearity limit	500 µg/l
Correlation (n=180)	Y = 0.94 x + 19.44 with a correlation coefficient r^2 = 0.9756.
Calibration stability	21 days
Reagent stability	closed stability: 12 months at 2-8°C on-board stability (refrigerated area): 35 days

CALIBRATORS

ABX PENTRA Myoglobin Cal:	
Analytes	Myoglobin
Format	Liquid preparation of diluted purified myoglobin positive human sera : 5 levels
Stability	Closed stability: 12 months at 2°C to 10°C Open stability: 7 weeks at 2°C to 10°C

ABX PENTRA Multical:		
Analytes	Already cleared	Included in this submission
Alkaline phosphatase	(K060205)	
Alanine aminotransferase	(CLIA)	
Amylase	(K062180)	
Aspartate aminotransferase	(K060318)	
Creatine kinase		
GGT	(CLIA)	
Lipase	(CLIA)	
Albumin*		
Direct Bilirubin	(K060325)	
Total Bilirubin	(K060325)	
Calcium	(K060205)	
Cholesterol	(K060854)	
Creatinine	(K060205)	
Glucose HK	(K052007)	
Glucose PAP	(K052007)	
Iron	(K060205)	
Lactic acid	(CLIA)	
Magnesium	(K060205)	
Phosphorus	(K060205)	
Total Protein*		
Triglycerides	(K060854)	
Urea / Blood Urea Nitrogen	(K060205)	
Uric acid	(K060205)	
		.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

CONTROLS

ABX PENTRA CK Control:	
Analytes	Total Creatine Kinase
Format	Lyophilized preparation of bovine serum albumin with chemical additives and material of animal origin
Stability	Closed stability: 18 months at 2°C to 8°C Open stability: 24 hours at 15°C to 25°C 3 days at 2°C to 8°C

ABX PENTRA Immuno II Control L/H:	
Analytes	Myoglobin
Format	Lyophilized preparation of bovine serum albumin with chemical additives and material of animal origin
Stability	Closed stability: 18 months at 2°C to 10°C Open stability: 2 weeks at 2°C to 10°C 3 months at –20°C

ABX PENTRA N Control:		
Analytes	Already cleared	Included in this submission
Alkaline phosphatase	(K060205)	
Alanine aminotransferase	(CLIA)	
Amylase	(K062180)	
Aspartate aminotransferase	(K060318)	
Creatine kinase		
GGT	(CLIA)	
Lipase	(CLIA)	
Albumin*		
Direct Bilirubin	(K060325)	
Total Bilirubin	(K060325)	
Calcium	(K060205)	
Chloride	(K052007)	
Cholesterol	(K060854)	
HDL	(K060854)	
LDL	(K060854)	
Creatinine	(K060205)	
Glucose HK	(K052007)	
Glucose PAP	(K052007)	
Iron	(K060205)	
Lactic acid	(CLIA)	
Magnesium	(K060205)	
Phosphorus	(K060205)	
Potassium	(K052007)	
Sodium	(K052007)	
Total Protein*		
Triglycerides	(K060854)	
Urea / Blood Urea Nitrogen	(K060205)	
Uric acid	(K060205)	
		.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

ABX PENTRA P Control:		
Analytes	Already cleared	Included in this submission
Alkaline phosphatase	(K060205)	
Alanine aminotransferase	(CLIA)	
Amylase	(K062180)	
Aspartate aminotransferase	(K060318)	
Creatine kinase		
GGT	(CLIA)	
Lipase	(CLIA)	
Albumin*		
Direct Bilirubin	(K060325)	
Total Bilirubin	(K060325)	
Calcium	(K060205)	
Chloride	(K052007)	
Cholesterol	(K060854)	
HDL	(K060854)	
LDL	(K060854)	
Creatinine	(K060205)	
Glucose HK	(K052007)	
Glucose PAP	(K052007)	
Iron	(K060205)	
Lactic acid	(CLIA)	
Magnesium	(K060205)	
Phosphorus	(K060205)	
Potassium	(K052007)	
Sodium	(K052007)	
Total Protein*		
Triglycerides	(K060854)	
Urea / Blood Urea Nitrogen	(K060205)	
Uric acid	(K060205)	
		.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Horiba ABX
c/o Pascal Macziola
Regulatory Affairs Manager
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
France

JUN 12 2007

Re: k062737
Trade/Device Name: ABX Pentra CK NAC CP, ABX Pentra Myoglobin CP, ABX Pentra CK Control, ABX Pentra Immuno II Control L/H, ABX Pentra Myoglobin Cal, ABX Pentra N Control, ABX Pentra P Control, ABX Pentra Multical
Regulation Number: 21 CFR § 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system.
Regulatory Class: Class II
Product Code: CGS, DDR, JIY, JIX, JIT
Dated: April 25, 2007
Received: April 30, 2007

Dear Pascal Macziola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Cardiac Markers on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

Cardiac Markers reagents, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure cardiac marker analytes.

ABX PENTRA CK-NAC CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of the total creatine kinase in human serum and plasma based on an optimized UV test.

Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

The ABX PENTRA CK Control is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA CK-MB RTU and ABX PENTRA CK-NAC methods.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

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Indications for Use

510(k) Number (if known):

Device Name: Cardiac Markers on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Myoglobin CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of myoglobin (an oxygen storage protein found in muscle) in human serum and plasma based on a latex-enhanced immunoturbidimetric assay.
Measurements of myoglobin aids in the rapid diagnosis of heart or renal disease.

The ABX PENTRA Myoglobin Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA Myoglobin CP method on Horiba ABX clinical chemistry analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

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Indications for Use

510(k) Number (if known):

Device Name: ABX PENTRA Immuno II Control L/H

Indications For Use:

The ABX PENTRA Immuno II Control L/H is for use in quality control by monitoring accuracy and precision.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known):

Device Name: ABX PENTRA Multical

Indications For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known):

Device Name: ABX PENTRA N Control

Indications For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known):

Device Name: ABX PENTRA P Control

Indications For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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